RXADVANCE
2 Park Central Drive
Southborough, MA 01772

NEW DRUG APPROVAL

Brand Name	ZILXI™
Generic Name	minocycline
Drug Manufacturer	Foamix Pharmaceuticals Inc.

New Drug Approval

ZILXI™ is a tetracycline-class drug indicated for the treatment of inflammatory lesions of rosacea in adults.

FDA Approval date: May 29, 2020

This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, ZILXI™ should be used only as indicated.

Place in Therapy

DISEASE DESCRIPTION & EPIDEMIOLOGY

Rosacea is a diverse skin condition that most commonly presents with symptoms such as deep facial redness, spider veins (telangiectasia) and acne-like inflammatory lesions (papules and pustules). Based on morphological characteristics, rosacea is generally classified into four major subtypes: erythematotelangiectatic, papulopustular, phymatous, and ocular.

Caucasians with fair sun-sensitive skin (skin phototypes I and II) appear to have the greatest risk for rosacea. It is unknown whether factors such as masking of facial redness by abundant skin pigment, protective effects of melanin against ultraviolet radiation (an exacerbating factor for rosacea), or genetic differences in susceptibility to rosacea contribute to the lower rate of diagnosis in people with darker skin. Estimates of the prevalence of rosacea in fair-skinned populations range from 2 to 22 percent.

Rosacea is most frequently seen in adults between 30 and 50 years of age. It affects more than 16 million people in the United States; up to 28% of these sufferers have rosacea with inflammatory lesions.

Efficacy

The safety and efficacy of once daily use of ZILXI™ was assessed in two 12-week multicenter, randomized, double-blind, vehicle-controlled trials in subjects with inflammatory lesions of rosacea (Trial 1 [NCT02601963] and Trial 2 [NCT03142451]).

Efficacy was assessed in a total of 1,522 subjects 18 years of age and older. Patients were randomized 2:1 to receive either ZILXI™ once daily or vehicle and were not permitted to use other topical or systemic medications to treat inflammatory lesions of rosacea during the trials.

The co-primary efficacy endpoints were the absolute change from baseline in inflammatory lesion counts at Week 12 and the proportion of subjects with treatment success at Week 12, defined as an IGA score of 0 (“clear”) or 1 (“almost clear”), and at least a two-grade improvement (decrease) from baseline at Week 12.

Safety

ADVERSE EVENTS

The most commonly observed adverse reaction (incidence ≥1%) is diarrhea.

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WARNINGS & PRECAUTIONS

- The use of tetracycline-class of drugs orally during the second and third trimesters of pregnancy, infancy and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.
- If Clostridioides difficile associated diarrhea occurs, discontinue ZILXI™.
- If liver injury is suspected, discontinue ZILXI™.
- If renal impairment exists, oral minocycline doses may need to be adjusted to avoid excessive systemic accumulations of the drug and possible liver toxicity.
- Oral minocycline may cause central nervous system side effects including light-headedness, dizziness, or vertigo.
- Oral minocycline may cause intracranial hypertension in adults and adolescents. Discontinue ZILXI™ if symptoms occur.
- Oral minocycline has been associated with autoimmune syndromes; discontinue ZILXI™ immediately if symptoms occur.
- Photosensitivity can occur with oral tetracycline. Patients should minimize or avoid exposure to natural or artificial sunlight.
- Oral minocycline has been associated with anaphylaxis, serious skin reactions, erythema multiforme, and DRESS syndrome. Discontinue ZILXI™ immediately if symptoms occur.
- The propellant in ZILXI™ is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application.

CONTRAINDICATIONS

- This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines or any of the ingredients in ZILXI™.

Clinical Pharmacology

MECHANISMS OF ACTION

The mechanism of action of ZILXI™ for the treatment of inflammatory lesions of rosacea is unknown.

Dose & Administration

ADULTS

Apply ZILXI™ to affected areas once daily. ZILXI™ should be gently rubbed into the skin.

PEDIATRICS

Safety and effectiveness of ZILXI™ for the treatment of inflammatory lesions of rosacea have not been evaluated in pediatric patients.

GERIATRICS

No overall differences in safety or effectiveness were observed between these subjects and younger subjects (refer to adult dosing).

RENAL IMPAIRMENT

If renal impairment exists, oral minocycline doses may need to be adjusted to avoid excessive systemic accumulations of the drug and possible liver toxicity.

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HEPATIC IMPAIRMENT

No dose adjustment provided in manufacturer's labelling.

Product Availability

DOSAGE FORM(S) & STRENGTH(S)

Topical Foam, 1.5%.